IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	:	10/642,272	Confirmation No.: 3248
Applicant	:	Fumiyuki HATTORI, *et al.*	
Filed	:	August 18, 2003	
Title	:	THERAPEUTIC METHODS AND AGENTS FOR DISEASES ASSOCIATED WITH DECREASED EXPRESSION OF AOP-1 GENE OR AOP-1	
TC/Art Unit	:	1632	
Examiner:	:	Marcia S. NOBLE, Ph.D.	
Docket No.	:	58777.000012	
Customer No.	:	**21967**	

MAIL STOP PATENT TERM EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(b)

Dear Sir:

Applicants request reconsideration under 37 C.F.R. § 1.705(b) of the patent term adjustment of 54 days indicated for the above-identified application ("the '272 application"). It is respectfully requested that Applicants be granted a minimum patent term adjustment of **512 days**.

The issue fee has not been paid in the '272 application. Accordingly, as required by 37 C.F.R. § 1.705(b), this request is timely.

In accordance with 37 C.F.R. § 1.705(b)(1), please charge the fee set forth in 37 C.F.R. § 1.18(e) ($200) to the undersigned's **Deposit Account No. 50-0206**. In the event any additional fees are required for consideration of this request, the USPTO is authorized to charge these fees to the undersigned's Deposit Account No. 50-0206.

Remarks begin on page 2.

REMARKS

Applicants request reconsideration under 37 C.F.R. § 1.705(b) of the patent term adjustment for the '272 application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of **512 days**.

Statement Under 37 C.F.R. § 1.705(b)(2)

The patent term adjustment ("PTA") under 35 U.S.C. § 154(b) listed on the '272 application is <u>54 days</u>. *See* **Exhibit A** (a copy of the Determination of Patent Term Adjustment). This determination is in error because the USPTO failed to take certain action within the time frame specified in 37 C.F.R. § 1.702(a) <u>and</u> failed to issue a patent within three years of the actual filing date of the above-identified patent application in accordance with 37 C.F.R. § 1.702(b). *See Wyeth v. Dudas* 88 USPQ2d 1538 (D.D.C. 2008).

A.   *Wyeth v. Dudas*

In *Wyeth v. Dudas*, the U.S. District Court for the District of Columbia considered the USPTO's interpretation of 35 U.S.C. § 154(b). This section provides three guarantees of patent term adjustment, two of which are at issue. The first is a one-day extension of patent term for every day that issuance is delayed due to the USPTO failure to comply with certain statutory deadlines such as fourteen months for a first office action. *See* 35 U.S.C. § 154(b)(1)(A)(i)-(iv); *see also* 37 C.F.R. § 1.702(a). These delays are called "A delays" or "A periods." The second adjustment is a one-day term extension for every day it takes the patent to issue after three years from the filing date. *See* 35 U.S.C. § 154(b)(1)(B); *see also* 37 C.F.R. § 1.702(b). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period."

Under the statute, if "A delays" and "B delays" overlap, "the period of adjustment granted ... shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A) The purpose of this section is to prevent "double-counting" of periods of delay. *See Wyeth*, 88 USPQ2d at 1539. According to the USPTO's interpretation of this section, any "A delay" overlaps with any "B delay," and thus an applicant can only get credit for an "A delay" *or* a "B delay," whichever is larger, but never for both. *Id.* at 1540. The court disagreed. It concluded that periods of time "overlap" *only* if they occur on the same day. *Id.* at 1541. Therefore, if an "A delay" and

a "B delay" occurs on a different day, then a patentee may obtain an extension of A + B days. *Id.*

B. Calculation of PTA Under 37 C.F.R. § 1.703 Under *Wyeth*

The following facts are relevant for determining PTA for the '756 application.

- August 18, 2003 – '272 application is filed.
- October 18, 2004 – the "fourteen month date" on which an Office Action should have been mailed (*i.e.*, beginning of "A period").
- January 13, 2006 – mail date of Restriction Requirement (*i.e.*, first office action)
- August 18, 2006 – three years from filing date of application (*i.e.*, beginning of "B period").
- November 19, 2007 - filing of a Request for Continued Examination (*i.e.*, end of "B period").
- February 6, 2009 – notice of allowance mailed.
- May 6, 2009 – due date for payment of issue fee

1. "A" Periods Under 37 C.F.R. § 1.702(a)

The number of days from the fourteen month date (October 18, 2004) to the mailing of a first office action (January 13, 2006) is 452 days. This is in agreement with the USPTO's calculations. *See* USPTO Patent Term Adjustment History, attached herewith as **Exhibit B**.

2. "B" Periods Under 37 C.F.R. § 1.702(b)

The number of days from the beginning of the "B period" (August 18, 2006, *i.e.*, three years from the filing day of the application) to the end of the proposed "B period" (November 19, 2007, *i.e.*, filing of a Request for Continued Examination) is 458 days.

3. Delay Attributed to Applicant

The USPTO has calculated Applicants' delay in this case as 398 days.

4. PTA = (A Period + B Period) – Applicants Delay

According to *Wyeth*, the PTA should be calculated as follows:

A period = 452 days. *See* 1. above

B period = 458 days. *See* 2. above.

Applicants' delay = 398 days. *See* 3 above.

$(452 + 458) - 398 = 512$ days

Accordingly, Applicants respectfully request that the '272 application be granted a minimum PTA of **512 days**.

CONCLUSION

In view of the above remarks, it is respectfully requested that this Request for Reconsideration of Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of **512 days**.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: May 5, 2009

By:
Robert M. Schulman
Registration No. 31,196

Christopher J. Nichols, Ph.D.
Registration No. 55,984

HUNTON & WILLIAMS LLP
Intellectual Property Department
1900 K Street, N.W., Suite 1200
Washington, D.C. 20006
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

Exhibit A
Determination of Patent Term Adjustment

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,272	08/18/2003	Fumiyuki Hattori	58777.000012	3248

21967   7590   02/06/2009

HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER
NOBLE, MARCIA STEPHENS

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/06/2009

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 54 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 54 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Exhibit B
USPTO Patent Term Adjustment History

10/642,272	THERAPEUTIC METHODS AND AGENTS FOR DISEASES ASSOCIATED WITH DECREASED EXPRESSION OF AOP-1 GENE OR AOP-1	05-05-2009::15:07:43

Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/642,272

Filing or 371(c) Date:	08-18-2003	USPTO Delay (PTO) Delay (days):	452
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	398
Post-Issue Petitions (days):	+0	Total PTA (days):	54
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
02-06-2009	Mail Notice of Allowance		
02-04-2009	Document Verification		
02-03-2009	Notice of Allowance Data Verification Completed		
02-02-2009	Examiner's Amendment Communication		
02-02-2009	Examiner Interview Summary Record (PTOL - 413)		
01-25-2009	Date Forwarded to Examiner		
01-15-2009	Amendment after Final Rejection		
10-15-2008	Mail Final Rejection (PTOL - 326)		
10-14-2008	Final Rejection		
08-28-2008	Date Forwarded to Examiner		
07-28-2008	Response after Non-Final Action		91
07-28-2008	Request for Extension of Time - Granted		⇧
08-20-2008	Mail Examiner Interview Summary (PTOL - 413)		⇧
08-12-2008	Examiner Interview Summary Record (PTOL - 413)		⇧
01-28-2008	Mail Non-Final Rejection		⇧
01-22-2008	Non-Final Rejection		
11-30-2007	Date Forwarded to Examiner		
11-19-2007	Request for Continued Examination (RCE)		94
11-30-2007	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		⇧
11-19-2007	Request for Extension of Time - Granted		⇧
11-19-2007	Workflow - Request for RCE - Begin		⇧
05-17-2007	Mail Final Rejection (PTOL - 326)		⇧
05-14-2007	Final Rejection		
02-09-2007	Information Disclosure Statement considered		
03-14-2007	Information Disclosure Statement considered		
04-10-2007	Information Disclosure Statement considered		
04-10-2007	Information Disclosure Statement (IDS) Filed		60
04-10-2007	Information Disclosure Statement (IDS) Filed		
03-14-2007	Information Disclosure Statement (IDS) Filed		⇧
03-14-2007	Information Disclosure Statement (IDS) Filed		⇧

Date	Description		
02-09-2007	Reference capture on IDS		⇧
02-09-2007	Information Disclosure Statement (IDS) Filed		⇧
02-09-2007	Information Disclosure Statement (IDS) Filed		⇧
02-09-2007	Miscellaneous Incoming Letter		⇧
03-09-2007	Date Forwarded to Examiner		⇧
02-09-2007	Response after Non-Final Action		92
02-09-2007	Request for Extension of Time - Granted		⇧
02-20-2007	CRF Is Flawed Technically / Not Entered into Database		⇧
08-09-2006	Mail Non-Final Rejection		⇧
08-07-2006	Non-Final Rejection		
06-20-2006	Date Forwarded to Examiner		
06-13-2006	Response to Election / Restriction Filed		61
06-13-2006	Request for Extension of Time - Granted		⇧
01-13-2006	Mail Restriction Requirement	452	
01-09-2006	Requirement for Restriction / Election	⇧	
12-04-2003	Information Disclosure Statement considered	⇧	
11-15-2005	Case Docketed to Examiner in GAU	⇧	
10-05-2005	IFW TSS Processing by Tech Center Complete	⇧	
10-05-2005	Mail Miscellaneous Communication to Applicant	⇧	
10-05-2005	Miscellaneous Communication to Applicant - No Action Count	⇧	
08-18-2003	Preliminary Amendment	⇧	
06-13-2005	Miscellaneous Incoming Letter	⇧	
05-05-2004	Miscellaneous Incoming Letter	⇧	
12-19-2003	Request for Foreign Priority (Priority Papers May Be Included)	⇧	
12-04-2003	Information Disclosure Statement (IDS) Filed	⇧	
12-04-2003	Information Disclosure Statement (IDS) Filed	⇧	
09-08-2005	Application Dispatched from OIPE	⇧	
09-08-2005	Application Is Now Complete	⇧	
08-24-2005	Additional Application Filing Fees	⇧	
08-24-2005	CRF Disk Has Been Received by Preexam / Group / PCT	⇧	
09-02-2005	CRF Is Good Technically / Entered into Database	⇧	
08-31-2005	SEQUENCE ERRORS	⇧	
07-18-2005	Correspondence Address Change	⇧	
06-24-2005	SEQUENCE ERRORS	⇧	
05-20-2004	SEQUENCE ERRORS	⇧	
08-18-2003	Additional Application Filing Fees	⇧	
08-18-2003	CRF Disk Has Been Received by Preexam / Group / PCT	⇧	
05-20-2004	Pre-Exam Office Action Withdrawn	⇧	
05-20-2004	SEQUENCE ERRORS	⇧	
08-18-2003	CRF Disk Has Been Received by Preexam / Group / PCT	⇧	

11-04-2003	Cleared by OIPE CSR	⬆
09-09-2003	CRF Is Flawed Technically / Not Entered into Database	⬆
09-03-2003	IFW Scan & PACR Auto Security Review	⬆
08-18-2003	CRF Disk Has Been Received by Preexam / Group / PCT	⬆
08-18-2003	Initial Exam Team nn	⬆

Close Window